

DETAILED ACTION

1. This is the initial Office action based on the 10/578,734 application filed on May 10, 2009, which is a 371 of PCT/SE04/01626 filed November 10, 2004, which claims Foreign Priority to SE 0302983-2 filed November 11, 2003.

Election/Restrictions

2. Applicant's election with traverse of Group I (Claims 1, 3, 5-52, 59, 60) in the reply filed on July 20, 2009 is acknowledged. The traversal is on the ground(s) that the applicant does not necessarily agree with the Examiner's characterizations of the claims and their elements and believes there is no serious burden. This is not found persuasive because groups I-IV do not relate to a single general inventive concept under PCT Rule 13.1 and share no special technical features claimed between the groups (see previous restriction requirement).

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

3. Applicant should note that the large number of references in the attached IDS have been considered by the examiner in the same manner as other documents in Office search files are considered by the examiner while conducting a search of the prior art in a proper field of search. See MPEP 609.05(b). The applicant is requested to fill in the 6th Column of the IDS (relevant passages/figures). The applicant is further requested to point out any particular references in the IDS which they believe may be of particular relevance to the instant claimed invention in response to this office action.

4. The information disclosure statement filed July 20, 2009 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Rejections - 35 USC § 101

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 9-10, 34-36 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 9, applicant positively recites part of a human, i.e. "device is located between the hole in the spongy bone" and in claim 10, "located between the monomer filter .. and the hole in the spongy bone." Claims 34 recites "spongy bone is a spongy vertebra," Claim 35 recites "bone is a fracture due to.." and Claim 36 recites "is a femoral or knee." Thus claims 9-10, 34-36 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. **Claims 1, 3, 5-52, 59-60** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, line 1, applicant recites "A device" with the hole in spongy bone only functionally recited. However, applicant positively recites "hole" as part of the invention, i.e. "material out of said hole", "sucked out of said hole" etc, thus indicating that the combination, device and the hole, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Since claiming the combination of the apparatus and the hole makes such claim(s) directed to non-statutory subject matter, applicant should amend the claims so as to remove all positive recitations of the hole. As such, the claim(s) would be directed to the subcombination, the device, and will be considered as such for examination purposes, wherein the hole is merely functionally recited.

Claim 1 also recites "reinforcing material in the whole without **said material** penetrating into the blood paths." There is insufficient preceding antecedent basis for "said material" in the claim, since it is unclear which material the applicant is referring to. The examiner further notes that claim 1 recites "after said rinsing agent and tissue

material have been sucked out ... without said material penetrating into the blood paths" recites part of the human being and is merely functional and/or intended use of the device. Claim 1 further recites "A device for providing .."

Claim 17 recites "a first and second cannula or needle are insertable .. such that **they** are simultaneously directed into the hole," which is unclear since the applicant is only claiming that only either the cannulas or the needle are insertable but then claims that both can be driven into the hole. Clarification is required and the examiner will treat with art as best understood.

8. Claims 41-43 each recite "wherein a device." There is insufficient antecedent basis for this limitation in the claim. It is unclear if the applicant meant to disclose the same device as in claim 1 or further comprising another device. Clarification is required and the examiner will treat with art as best understood.

9. Regarding claim 46, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. **Claims 1, 3, 11-13, 17-18, 20-21, 26-29, 32-37, 41-45, 51-52, 60** are rejected under 35 U.S.C. 102(b) as being anticipated by Reiley et al US 6,248,110.

Regarding **Claim 1**, Reiley discloses a device for providing spongy bone with bone substitute and/or bone reinforcing material, wherein:

at least one perforating device (#76 as seen in Fig 5h) is provided for making at least one hole in the spongy bone,

at least one flushing or rinsing device (#82 as seen in Fig 4 and see also Col 8 lines 52-60) is provided for flushing or rinsing the hole with a rinsing agent,

at least one supply device (#96 as seen in Fig 5m and see Col 9 lines 7-20) is provided for permitting supply of bone substitute and/or bone reinforcing material to the hole in the spongy bone, and

at least one vacuum source (#86 as seen in Fig 4 and see also Col 8 lines 52-60 and a vacuum source at #94, see Col 9 lines 7-18, 35-45, wherein the material can be distributed) is provided for generating a vacuum in the hole in the spongy bone for sucking rinsing agent into said hole and rinsing agent and tissue material out of said hole, wherein

that vacuum source is provided also to generate a vacuum which is adapted for sucking and/or facilitating insertion or feeding of the bone substitute and/or bone reinforcing material into the hole in the spongy bone after rinsing agent and tissue material have been sucked out of said hole and for distributing the bone substitute and/or bone reinforcing material in the hole without said material penetrating into the blood paths (see Col 9 lines 7-18, where the vacuum source can distribute material).

Regarding **Claim 3**, Reiley discloses the vacuum source (#94) is provided to generate a vacuum in the hole of the spongy bone which is adapted such that the bone

substitute and/or bone reinforcing material is sucked into said hole and distributed therein without substantial portions thereof being sucked out of the hole (see Col 9 lines 7-18, 35-45, wherein the material can be distributed without portions being sucked out of the hole).

Regarding **Claim 11**, Reiley discloses a container (#94 as seen in Fig 5m) for producing and/or storing bone substitute and/or bone reinforcing material is provided with a feeding device (#92) for feeding bone substitute and/or bone reinforcing material out of the container and into the hole of the spongy bone at the same time the vacuum source generates a vacuum therein.

Regarding **Claim 12**, Reiley discloses a container and a feeding device (#94 and #92 respectfully as seen in Fig 53).

Regarding **Claim 13**, Reiley discloses the feeding device is manually operated (see Col 9 lines 7-18).

Regarding **Claim 17**, Reiley discloses a first (#72) and a second cannula (#50) or needle (#66) are insertable into the spongy bone such that they are simultaneously directed into the hole (as seen in Fig 5j) thereof and that the first cannula or needle is connected to a container (#94) for producing and/or storing the bone substitute and/or bone reinforcing material while the second cannula or needle is connected to the vacuum source (#86 as seen in Fig 5j and Fig 4, where the vacuum source can be connected to the vacuum source).

Regarding **Claim 18**, Reiley discloses the flushing or rinsing device comprises a rinsing agent container (#82) which is connected to the first cannula or needle (as seen

in Fig 5j) for leading rinsing agent into the hole of the spongy bone through said first cannula and out of said hole to the second cannula or needle (as seen in Fig 5j).

Regarding **Claim 20**, Reiley discloses the rinsing device is provided to flush or rinse the sides of the hole so that tissue material and other material are flushed away therefrom such that depressions are formed therein, into which the bone substitute and/or bone reinforcing material can penetrate (see rejection in claim 1 and see Col 8 lines 52-58 where the rinsing device can flush away tissue and other material).

Regarding **Claim 21**, Reiley discloses vacuum source is provided to suck rinsing agent through the hole in the spongy bone (see rejection in claim 1 and see Col 8 lines 52-58 where the rinsing device can flush away tissue and other material as well as Fig 4).

Regarding **Claim 26**, Reiley discloses wherein the perforating device can be provided with or comprises several units for making at least two holes (#76, #66) in the spongy bone either by said holes extending into each other or by having such spongy bone between them which can be penetrated by air and provided with bone substitute and/or bone reinforcing material (wherein the perforating device can make any number of holes if one chooses to do).

Regarding **Claim 27-29**, Reiley discloses the vacuum source is an injector pump (see Col 8 lines 52-55) which is operated by a compressed medium, wherein the injector pump (21) can be connected to a compressed-medium device which is

designed as a compressed-air device which is provided in localities in or close to which the vacuum source shall be used (see Fig 4 and see Col 8 lines 52-55, where air is used).

Regarding **Claim 32**, Reiley discloses the vacuum source (#86) is a pump operated by gas (see Col 8 line 52-55).

Regarding **Claim 33**, Reiley discloses the vacuum source (#94) is operated by hand (see Col 9 lines 7-18).

Regarding **Claims 34-36**, Riley discloses wherein the spongy bone is a spongy vertebra, a fracture due to osteoporosis, the spongy bone is a femoral or knee fracture (the examiner notes that this limitation is functional, see 101 rejection above as well, wherein the device of Riley can be used on vertebra, a fracture due to osteoporosis or a femoral or knee fracture).

Regarding **Claim 37**, Riley discloses the rinsing agent is a sodium chloride solution (see Col 8 lines 34-35, where saline can be used).

Regarding **Claim 41**, Riley discloses device (#98) for imparting pulse like suction and/or insertion movements to the bone substitute and/or bone reinforcing material into the hole in the spongy bone (see col 9 lines 7-15, 25-30, where one can grip the device for insertion movements into a hole).

Regarding **Claim 42**, Riley discloses device (#98) for imparting pulse like suction and/or insertion movements to the bone substitute and/or bone reinforcing material into

the hole in the spongy bone (see col 9 lines 7-15, 25-30, where one can grip the device for insertion movements into a hole).

Regarding **Claim 43**, Riley discloses a device (#50) for pulse like suction and/or feeding of the rinsing agent through the hole in the spongy bone (see Fig 4, where the device can feed rinsing agent to a hole).

Regarding **Claim 44-45, 51-52, 60** , Riley discloses the use of a mineral such as: bone cement, MMA type or synthetic bone substitute (see col 9 lines 10-13).

12. **Claims 1, 21-22** are rejected under 35 U.S.C. 102(b) as being anticipated by Andrew et al US 6,074,358.

Andrew discloses a device for providing spongy bone with bone substitute and/or bone reinforcing material, wherein:

at least one perforating device (see Col 4 lines 29-30, where there are means for making a hole) is provided for making at least one hole in the spongy bone,

at least one flushing or rinsing device (#34, see Fig 1) is provided for flushing or rinsing the hole with a rinsing agent,

at least one supply device (#34, see Fig 1) is provided for permitting supply of bone substitute and/or bone reinforcing material to the hole in the spongy bone, and

at least one vacuum source (#37) is provided for generating a vacuum in the hole in the spongy bone for sucking rinsing agent into said hole and rinsing agent and tissue material out of said hole, wherein

that vacuum source is provided also to generate a vacuum which is adapted for sucking and/or facilitating insertion or feeding of the bone substitute and/or bone reinforcing material into the hole in the spongy bone after rinsing agent and tissue material have been sucked out of said hole and for distributing the bone substitute and/or bone reinforcing material in the hole without said material penetrating into the blood path, a vacuum source is provided to suck rinsing agent through the hole in the spongy bone, wherein the vacuum source (#120) is the same vacuum source which is used for sucking and/or facilitating insertion or feeding of bone substitute and/or bone reinforcing material (see Fig 1 and see Col 3 lines 40-45, where the device can deliver rinsing fluid and other materials into a bone, Col 4 lines 14-20 where the vacuum source can aspirate fluid out).

13. **Claims 1, 23** are rejected under 35 U.S.C. 102(b) as being anticipated by Reiley et al US 6,248,110.

Regarding **Claim 1**, Reiley discloses a device for providing spongy bone with bone substitute and/or bone reinforcing material, wherein:

at least one perforating device (#72, #76 as seen in Fig 5h) is provided for making at least one hole in the spongy bone,

at least one flushing or rinsing device (#82 as seen in Fig 4 and see also Col 8 lines 52-60) is provided for flushing or rinsing the hole with a rinsing agent,

at least one supply device (#96 as seen in Fig 5m and see Col 9 lines 7-20) is provided for permitting supply of bone substitute and/or bone reinforcing material to the hole in the spongy bone, and

at least one vacuum source (#86 as seen in Fig 4 and see also Col 8 lines 52-60 and that vacuum source at #94 as seen in Fig 5m and see Col 9 lines 7-18) is provided for generating a vacuum in the hole in the spongy bone for sucking rinsing agent into said hole and rinsing agent and tissue material out of said hole, wherein

that vacuum source is provided also to generate a vacuum which is adapted for sucking and/or facilitating insertion or feeding of the bone substitute and/or bone reinforcing material into the hole in the spongy bone after rinsing agent and tissue material have been sucked out of said hole and for distributing the bone substitute and/or bone reinforcing material in the hole without said material penetrating into the blood paths (see Col 9 lines 7-18, where the vacuum source can distribute material).

Regarding **Claim 23**, Reiley discloses the perforating device comprises an outer tube member (#72) which can be located at the spongy bone, and a perforating means (#76) which is movable in said outer tube member (#72) in coaxial and/or rotary direction and which includes and/or cooperates with a perforating member (#76) for making the hole in the spongy bone (see Fig 5h, see Col 7 lines 55-58) wherein the perforating device has an outer tubular member which is slid over perforating means .

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. **Claim 38-40, 59** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11.

Reiley discloses the claimed invention as discussed above but does not disclose the rinsing agent contains a detergent, at least one trombolytic substance, or distilled water, at least one trombolytic substance is chosen from heparin, streptokinase, urokinase, TPA, and other substances dissolving coagulum and thrombi, and mixtures thereof.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Reiley to have the rinsing agent contain the materials listed above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

18. **Claim 46-50** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11.

Reiley discloses the claimed invention as discussed above but does not disclose the material is a mineral or ceramic material that can harden with a liquid, the mineral material or ceramic is selected from the group comprising calcium sulphate-.alpha.-hemihydrate, calcium sulphate-.beta.-hemihydrate, calcium sulphate-dihydrate, calcium carbonate, .alpha.-tricalcium phosphate, hydroxyapatite, dicalcium phosphate-dihydrate, anhydrous dicalcium phosphate, tetracalcium phosphate, .beta.-tricalcium phosphate, calcium deficient hydroxyapatite, monocalcium phosphate-monohydrate, mono-calcium phosphate, calcium-pyrophosphate, precipitated hydroxyapatite, carbonaceous apatite (dahlite), octa-calcium phosphate, amorphous calcium phosphate, oxyapatite, carbonate apatite and calcium aluminate, an X-ray contrast agent is mixed with the ceramic material, wherein the X-ray contrast agent is water soluble and non-ionic, wherein the water soluble, non-ionic X-ray contrast agent is selected from the group comprising iohexol, ioversol, iopamidol, iotrolan, metrizamide, iodecimol, iogluconol, iogluconamide, iogluconide, iogluconamide, iomeprol, iopentol, iopromide, iosarcosine, iosimide, iotusol, ioxilan, iofrolan and iodecol.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Reiley to have the reinforcing material to include the materials selected from those listed above, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

19. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11 in view of Bonnutti US 5,269,785.

Riley discloses the claimed invention as discussed above but does not disclose a collecting device.

However, Bonnutti discloses a rinsing and vacuum device (as seen in Fig 1, #22) with a collecting device (#28) use to draw in tissue fragments during irrigation (see Col 5 lines 55-60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Reiley to include the collecting device in view of Bonnutti in order to draw in tissue fragments during rinsing/irrigation.

20. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11 and Bonnutti US 5,269,785, as applied to claim 5 above, and further in view of Fischer US 3,965,910.

The combination of Riley and Bonnutti disclose the claimed invention as discussed above but does not disclose a non-return valve.

However, Fischer discloses an irrigation system with a non return valve (#30) such that when the irrigation system is withdrawn, it prevents drainage from a collecting

device from re-entering back into the body thus reducing infection (see Col 3 lines 66-68 Col 4 lines 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Riley and Bonnutti to include a non return valve in view of Fishcher in order to prevent drainage from re-entering the body, thus reducing the chance of infection.

21. **Claim 6** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11 in view of Nies et al US 5,997,544

Riley discloses the claimed invention as discussed above but does not disclose a monomer filter.

However, Nies discloses the use of a monomer filter which is used to help keep a sterilized package bone cement (see 2 lines 50-55).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Reiley to include a filter in view of Nies in order to keep bone cement sterile.

22. **Claims 5, 7** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11 in view of McDonald et al US 3,837,379.

Riley discloses the claimed invention as discussed above but does not disclose a bacteria filter.

However, McDonald discloses the use of a filter in order to prevent bacteria and other organisms to enter irrigation liquid (see Col 4 lines 59-65).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Riley to include a bacteria filter in view of McDonald in order to prevent entrance of bacteria and other microorganisms.

23. **Claim 10** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11 and McDonald et al US 3,837,379, as applied to claim 5 above, and further in view of Fischer US 3,965,910.

The combination of Riley and McDonald disclose the claimed invention as discussed above but does not disclose a non-return valve.

However, Fischer discloses an irrigation system with a non return valve (#30) located between a conduit to the body and an irrigation system, such that when the irrigation system is withdrawn, it prevents from re-entering back into the body thus reducing infection (see Col 3 lines 66-68 Col 4 lines 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Riley and McDonald to include a non return valve in view of Fishcher in order to prevent drainage from re-entering the body, thus reducing the chance of infection.

24. **Claim 8** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11 in view of Fischer US 3,965,910.

Reiley discloses the claimed invention as discussed above but does not disclose a non-return valve.

However, Fischer discloses an irrigation system with a non return valve (#30) such that when the irrigation system is withdrawn, it prevents drainage from re-entering back into the body thus reducing infection (see Col 3 lines 66-68 Col 4 lines 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Riley to include a non return valve in view of Fishcher in order to prevent drainage from re-entering the body, thus reducing the chance of infection.

25. **Claim 14-15** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11.

Reiley discloses the claimed invention as discussed above but does not disclose the vacuum source can generate a vacuum between .5 bar and .92 bar, .7 and .8 bar.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the vacuum generate a vacuum between .5 bar and .92 bar, .7 and .8 bar, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

26. **Claim 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11 in view of Voellmicke US 2002/0156483.

Reiley discloses the claimed invention as discussed above but does not disclose a valve device.

However, Voellmicke teaches the use of a valve device which opens and closes at certain pressures to allow material to be injected under high pressure and closed

during low pressure, so that material can not be sucked back during refilling (see paragraph 133).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Reiley to include a valve in view of Voellmicke so that under low pressure material can not be sucked back in.

27. **Claim 19** is rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,111 in view of Fischer US 3,965,910.

Riley discloses the claimed invention as discussed above but does not disclose a valve device for the rinsing agent.

However, Fischer discloses an irrigation system with a return valve (#30) to control fluid movement and prevent drainage from a collecting device from re-entering back into the body thus reducing infection (see Col 3 lines 66-68 Col 4 lines 1-5).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Riley to include a valve in view of Fishcher in order to control fluid movement and prevent drainage from re-entering the body, thus reducing the chance of infection.

28. **Claim 24-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,110 in view of Bonutti US 5,269,785.

Riley discloses the claimed invention as discussed above where the perforating means (#76) is movable in the outer tube but does not disclose an inner tube member for leading rinsing agent and the inner tube member connected to a vacuum source for sucking the rinsing agent, wherein the inner tube is connected to a vacuum source

However, Bonutti discloses a perforating means (#18) with an inner tube member (#36) for leading rinsing agent (#22) in and the vacuum member (#26), wherein the inner tube member is connected to the vacuum source for sucking rinsing agent, wherein it allows material to be cut while suctioning cut fragments out at the same time (see Col 4 lines 1-20, Col 5 lines 54-60).

It would have been obvious to one having ordinary skill in the art at the invention was made to modify device of Reiley to have the perforating means comprising an inner tube and the vacuum source connected to the inner tube and rinsing agent in view of Bonutti because it applies a known technique to a known device ready for improvement to allow material to be cut while suctioning cut fragments out at the same time.

29. **Claim 30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,110.

Riley discloses the claimed invention as discussed above wherein the injector pump can be connected to a compressed-medium device (see above) but does not disclose that it can operate said pump with a compressed-medium pressure of 4.5-8.5 bar.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have the generate a compressed-medium pressure of 4.5-8.5 bar, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

30. **Claim 31** are rejected under 35 U.S.C. 103(a) as being unpatentable over Reiley et al US 6,248,11 in view of Sproul US 2004/0006347.

Reiley discloses the claimed invention as discussed above but does not disclose the vacuum source is electrically operated.

However, Sproul discloses a vacuum source that is electrically operated (see paragraph 32), which has a control unit to control the power of the vacuum (#109).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Reiley to be electrically operated in view of Sproul because it applies a known technique to a known device ready for improvement to yield predictable results of powering and controlling a vacuum source.

Conclusion

The prior art made of record and relied upon is considered pertinent to the applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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